K060538

Section 5.0
510(k) Summary

Beaverite Body Fat Scales

Submitter Name:	Beaverite International Ltd
Submitter Address:	West Wing, 8/F CNT Group Building 822 Lai Chi Kok Road Cheung Sha Wan, Kowloon, Hong Kong
Contact Person:	Patsy J. Trisler, J.D., RAC Regulatory Consultant – Medical Devices
Phone Number:	301-652-5344
Fax Number:	301-654-6976
Date:	September 25, 2006
Device Trade Name:	Beaverite Body Fat Scales
Device Common Name:	Analyzer, Body Composition
Classification Name:	Impedance Plethysmograph
Classification Number:	21 CFR 870.2770
Product Code:	MNW
Predicate Device:	Tanita Innerscan Body Composition Monitor, K040778
Statement of Intended Use:	The Beaverite Body Fat Scales -- Models 8921, 8925, 8931, 8935 and 9576 -- measure body weight and impedance, and estimate percentages of body fat and total body water. They are intended for use by healthy adults. The Beaverite Body Fat Scales -- Models 8919, 8923, 8929, 9580, 9583, and 9588 -- measure body weight and impedance, and estimate percentages of body fat, total body water, and total muscle mass. They are intended for use by healthy adults.
Device Description, Summary of Technological Characteristics, and Comparison to the Predicate Device	The 11 models of Beaverite body fat scales submitted in this 510(k) are plethysmograph body composition analyzers. The devices estimate percentages of body fat, body water and muscle mass (as noted in the Indications statement) based on bioelectrical impedance analysis (BIA). The following table illustrates the substantial equivalence in technology and intended use to the predicate device.

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Feature	Proposed Device: Beaverite Body Fat Scales	Predicate Device: Tanita InnerScan Body Composition Monitor (Model BC-533)
510(k) Number		K040778
Manufacturer	Beaverite International Ltd	Tanita Corp of America
Classification # Product Code	21 CFR 870.2770 MNW	21 CFR 870.2770 MNW
Indications for Use	The Beaverite Body Fat Scales -- Models 8921, 8925, 8931, 8935 and 9576 -- measure body weight and impedance, and estimate percentages of body fat and total body water. They are intended for use by healthy adults. The Beaverite Body Fat Scales -- Models 8919, 8923, 8929, 9580, 9583, and 9588 -- measure body weight and impedance, and estimate percentages of body fat, total body water, and total muscle mass. They are intended for use by healthy adults.	The Tanita family of InnerScan Body Composition Monitors measure body weight and impedance and estimate percentage of body fat and body water, visceral fat rating, bone mass, muscle mass, physique rating, daily caloric intake (DCI) and metabolic age using BIA. They are intended for use by healthy children 7-17 years old and healthy adults with active, moderately active, to inactive lifestyles for body composition assessment in the home environment.
Device description	Body composition analyzer/scale that utilizes a 'foot-to-foot' bioelectrical impedance (BIA) technology to determine internal body composition.	Body composition analyzer/scale that utilizes a 'foot-to-foot' bioelectrical impedance (BIA) technology to determine internal body composition.
Analysis Method	BIA	BIA
Operating Parameters	20 KHz (Models 8923, 8929) 54 KHz (Models 8919, 8921, 8925, 8931, 8935, 9576, 9580, 9583, 9588)	54 KHz
Power source	Replaceable 9V or 3V batteries, depending on the model.	AA batteries
Operating keys	Range of 2 to 5, depending on the model.	13
Number of electrodes	4 (except for Model 8929 = 2)	4

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

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Patsy J. Trisler, J.D., R.A.C.
Regulatory Consultant – Medical Devices
Beaverite International Ltd.
5600 Wisconsin Avenue., Suite 509
CHEVY CHASE MD 20815

Re: K060538
Trade/Device Name: Beaverite Body Fat Scales; Models 8919, 8921, 8923, 8925, 8929, 8931, 8935, 9576, 9580, 9583 and 9588
Regulation Number: 21 CFR §870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: MNW
Dated: September 25, 2006
Received: September 25, 2006

Dear Ms. Trisler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060538

Device Name: Beaverite Body Fat Scales

Indications for Use:

The Beaverite Body Fat Scales -- Models 8921, 8925, 8931, 8935 and 9576 -- measure body weight and impedance, and estimate percentages of body fat and total body water. They are intended for use by healthy adults.

The Beaverite Body Fat Scales -- Models 8919, 8923, 8929, 9580, 9583, and 9588 -- measure body weight and impedance, and estimate percentages of body fat, total body water, and total muscle mass. They are intended for use by healthy adults.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060538

(Posted November 13, 2003)